who later tests reactive for evidence of HCV infection.

(5) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the further testing performed under paragraph (b)(2) of this section or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA.

(c) If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions, which you must complete within 1 year of the date of notification by the collecting establishment:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (b)(1)(iii) of this section, except pooled blood components solely intended for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the further testing performed under paragraph (b)(2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HCV is positive; or the supplemental test is indeterminate, but the supplemental test is known to be less sensitive than the screening test; or the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA; or if supplemental testing is not performed, you must make reasonable attempts to notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, or the recipient's physician of record, of the need for recipient HCV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient.

(d) Actions under this section do not constitute a recall as defined in §7.3 of this chapter.

(e) This section will expire on August 24, 2015.

[72 FR 48800, Aug. 24, 2007]

Subpart F—Dating Period Limitations

§ 610.50 Date of manufacture.

The date of manufacture shall be determined as follows:

(a) For products for which an official standard of potency is prescribed in either §610.20 or §610.21, or which are subject to official potency tests, the date of initiation by the manufacturer of the last valid potency test.

(b) For products that are not subject to official potency tests, (1) the date of removal from animals, (2) the date of extraction, (3) the date of solution, (4) the date of cessation of growth, or (5) the date of final sterile filtration of a bulk solution, whichever is applicable.

[38 FR 32056, Nov. 20, 1973, as amended at 42 FR 27582, May 31, 1977]

§ 610.53 Dating periods for licensed biological products.

(a) *General.* The minimum dating periods in paragraph (c) of this section are based on data relating to usage, clinical experience, or laboratory tests that establish the reasonable period beyond which the product cannot be expected to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter are designed to ensure the continued safety, purity, and potency of the products and are based

on the dating periods set forth in paragraph (c) of this section. Package labels for each product shall recommend storage at the stated temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the table in this paragraph, a product in column A may be stored by the manufacturer at the prescribed temperature and length of time in either column B or C, plus the length of time in column D. The dating period in column D shall be applied from the day the product leaves the manufacturer's storage, provided the product has not exceeded its maximum storage period, as prescribed in column B or C. If a product is held in the manufacturer's storage beyond the period prescribed, the dating period for the product being distributed shall be reduced by a corresponding period.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Adenovirus Vaccine Live Oral	6 months	Not applicable	6 months.
Albumin (Human)	3 years	...do	(a) 5 years.
	...do	...do	(b) 3 years, provided labeling recommends storage at room temperature, no warmer than 37 °C.
	Not applicable	...do	(c) 10 years, if in a hermetically sealed metal container and provided labeling recommends storage between 2 and 8 °C.
Allergenic Extracts labeled "No U.S. Standard of Potency":			
1. With 50 percent or more glycerin.	3 years	...do	3 years.
2. With less than 50 percent glycerin.	18 months	...do	18 months.
3. Products for which cold storage conditions are inappropriate.	Not applicable	...do	18 months (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
4. Powders and tablets	...do	...do	5 years (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
5. Freeze-dried products:			
a. Unreconstituted	...do	...do	4 years (from date of manufacture).
b. Reconstituted	...do	...do	18 months (cannot exceed 4-year unreconstituted dating period plus an additional 12 months).
Allergenic Extracts, Alum Precipitated labeled "No U.S. Standard of Potency".	18 months	...do	18 months.
Anthrax Vaccine Adsorbed	2 years	...do	1 year.
Antibody to Hepatitis B Surface Antigen:			
1. Antibody to Hepatitis B Surface Antigen.	6 months	...do	6 months.
2. Lyophilized coated red blood cells.	...do	...do	Do.
3. Enzyme conjugated products	...do	...do	Do.
Iodinated (^{125}I) products	Not applicable	...do	45 days (from date of manufacture).
Antihemophilic Factor (Human)	...do	...do	1 year (from date of manufacture).
Anti-Human Globulin Liquid	...do	...do	2 years.
Anti-Inhibitor Coagulant Complex	...do	...do	Do.
Antirabies Serum	1 year	...do	Do.
Antivenin (*Crotalidae*) Polyvalent	...do	...do	5 years with an initial 10 percent excess of potency, provided labeling recommends storage at 37 °C or colder.
Antivenin (*Latrodectus Mactans*)	...do	...do	5 years with an initial 10 percent excess of potency.
Antivenin (*Micurus fulvius*)	...do	...do	Do.
Asparaginase	Not applicable	...do	18 months from the date of the last valid potency test.
BCG Vaccine	1 year	Not applicable	6 months.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Blood Grouping Reagents			
1. Liquid	Not applicable	Not applicable	2 years.
2. Dried	1 year	2 years	5 years.
Blood Group Substance AB	do	do	2 years.
Blood Group Substance A	do	do	Do.
Blood Group Substance B	do	do	Do.
Botulism Antitoxin	do	Not applicable	5 years with an initial 20 percent excess of potency.
Cholera Vaccine	do	do	18 months.
Coccidioidin	do	do	3 years.
Collagenase	Not applicable	do	4 years (from date of manufacture), provided labeling recommends storage at 37 °C or colder.
Cryoprecipitated AHF	do	do	12 months from the date of collection of source blood, provided labeling recommends storage at −18 °C or colder.
Diphtheria Antitoxin:			
1. Liquid	1 year	do	5 years with an initial 20 percent excess of potency.
2. Dried	do	2 years	5 years with an initial 10 percent excess of potency.
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed.	do	Not applicable	18 months.
Diphtheria and Tetanus Toxoids, Adsorbed.	do	do	2 years.
Diphtheria Toxin for Schick Test	do	do	1 year.
Diphtheria Toxoid	do	do	2 years.
Diphtheria Toxoid Adsorbed	do	2 years	Do.
Diphtheria Toxoid-Schick Test Control	Not applicable	Not applicable	1 year.
Factor IX Complex	do	do	1 year (from date of manufacture).
Fibrinolysin (Human)	1 year	2 years	2 years.
Fibrinolysin and Desoxyribonuclease Combined (Bovine).	do	do	3 years, provided labeling recommends storage at 30 °C or colder.
Fibrinolysin and Desoxyribonuclease Combined (Bovine) with Chloramphenicol.	do	do	Do.
Hepatitis B Surface Antigen:			
1. Unlyophilized coated red blood cells.	Not applicable	do	14 days (from date of manufacture).
2. Iodinated (^{125}I) product	do	do	45 days (from date of manufacture).
3. Enzyme conjugated product	6 months	do	6 months.
Histoplasmin	1 year	Not applicable	2 years.
Immunoglobulins:			
1. Hepatitis B Immune Globulin (Human).	Not applicable	do	1 year.
2. Immune Globulin (Human)	3 years	do	3 years.
3. Immune Globulin Intravenous (Human).	Not applicable	do	1 year.
4. Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine).	do	Not applicable	2 years.
5. Pertussis Immune Globulin (Human).	3 years	do	3 years from date the dried or frozen bulk product is placed in final solution.
6. Rabies Immune Globulin (Human).	1 year	do	1 year.
7. Rh_o(D) Immune Globulin (Human).	6 months	do	6 months.
8. Tetanus Immune Globulin (Human).	1 year	do	3 years with an initial 10 percent excess of potency.
9. Vaccinia Immune Globulin (Human).	3 years	do	3 years.
10. Varicella-Zoster Immune Globulin (Human).	Not applicable	do	1 year.
Hepatitis B Vaccine	2 years at 2 to 8 °C.	Not applicable	3 years.
Influenza Virus Vaccine	1 year	do	18 months.
Limulus Amebocyte Lysate	Not applicable	Not applicable	18 months (from date of manufacture).
Measles, Mumps, and Rubella Virus Vaccine Live.	do	1 year (−20 °C or colder).	1 year.
Measles and Mumps Virus Vaccine Live	do	do	1 year.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Measles and Rubella Virus Vaccine Live ..	.....do	.....do	Do.
Measles Live and Smallpox Vaccine	Not applicable	.....do	1 year (from date of manufacture).
Measles Virus Vaccine Live	.....do	.....do	1 year.
Meningococcal Polysaccharide Vaccine Group A:			
1. Final bulk powder	.....do	2 years (−20 °C or colder).	Not applicable.
2. Final container	Not applicable	3 years (−20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Group C:			
1. Final bulk powder	.....do	2 years (−20 °C or colder).	Not applicable.
2. Final container	.....do	3 years (−20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Groups A and C combined:			
1. Final bulk powder	.....do	2 years (−20 °C or colder).	Not applicable.
2. Final container	.....do	3 years (−20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Groups A, C, Y, and W135 combined:			
1. Final bulk power	.....do	2 years (−20 °C or colder).	Not applicable.
2. Final container	.....do	3 years (−20 °C or colder).	2 years.
Mumps Skin Test Antigen	6 months	Not applicable	18 months.
Mumps Virus Vaccine Live	Not applicable	1 year (−20 °C or colder).	1 year.
Normal Horse Serum	1 year	2 years	5 years.
Pertussis Vaccine	.....do	Not applicable	18 months.
Pertussis Vaccine Adsorbed	.....do	.....do	Do.
Plague Vaccine	.....do	.....do	Do.
Plasma products:			
1. Fresh Frozen Plasma	Not applicable	.....do	1 year from date of collection of source blood (−18 °C or colder).
2. Liquid Plasma	.....do	.....do	(a) 26 days from date of collection of source blood (between 1 and 6 °C). (b) 40 days from date of collection of source blood only when CPDA–1 solution is used as the anticoagulant (between 1 and 6 °C).
3. Plasma	.....do	.....do	5 years from date of collection of source blood (−18 °C or colder).
4. Platelet Rich Plasma	.....do	.....do	72 hours from time of collection of source blood, provided labeling recommends storage (20 to 24 °C or between 1 and 6 °C). 5 days if certain approved containers are used (20 to 24 °C).
5. Source Leukocytes	.....do	.....do	In lieu of expiration date, the collection date shall appear on the label.
6. Source Plasma	.....do	.....do	10 years (at the recommended storage temperature stated on the label).
7. Therapeutic Exchange Plasma	.....do	.....do	10 years.
Plasma Protein Fraction (Human)	1 year	.....do	(a) 5 years. (b) 3 years provided labeling recommends storage at room temperature, no warmer than 30 °C).
Platelets	Not applicable	.....do	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24 °C or between 1 and 6 °C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research (CBER).

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Pneumococcal Vaccine Polyvalent:			
1. Final bulk powder	.....do	24 months after potency assay (−20 °C or colder).	Not applicable.
2. Final container	.....do	Not applicable	2 years (from date of manufacture).
Poliovirus Vaccine Inactivated	1 year	.....do	1 year.
Poliovirus Vaccine Live Oral Trivalent:			
1. Frozen	Not applicable	1 year (−10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	.....do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type I:			
1. Frozen	.....do	1 year (−10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	.....do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type II:			
1. Frozen	.....do	1 year (−10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	.....do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type III:			
1. Frozen	.....do	1 year (−10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	.....do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Polyvalent bacterial antigens with "No U.S. Standard of Potency" liquid.	1 year	.....do	18 months.
Polyvalent bacterial vaccines with "No U.S. Standard of Potency" liquid.	.....do	.....do	Do.
Rabies Vaccine:			
1. Dried	.....do	2 years	Do.
2. Liquid	3 months	Not applicable	6 months.
Reagent red blood cells	Not applicable	Not applicable	Thirty-five days from earliest date of collection if kept in liquid form (indefinite storage of reagent red blood cell source material at −65 °C or colder).
ACD Red Blood Cells	.....do	.....do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPD Red Blood Cells	.....do	.....do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
CPDA–1 Red Blood Cells	.....do	.....do	(a) 35 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
Red Blood Cells Deglycerolized	.....do	.....do	24 hours after removal from storage at −65 °C or colder, provided labeling recommends storage between 1 and 6 °C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.
Red Blood Cells Frozen	.....do	.....do	10 years from date of collection of source blood, provided labeling recommends storage at −65 °C or colder, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.
Rubella and Mumps Virus Vaccine Live	.....do	1 year (−20 °C or colder).	1 year.
Rubella Virus Vaccine Live	.....do	.....do	Do.
Skin Test Antigens for Cellular Hypersensitivity.	6 months	Not applicable	Do.
Smallpox Vaccine:			
1. Liquid	Not applicable	9 months (−10 °C or colder, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers).	3 months, provided labeling recommends storage at 0 °C or colder.
2. Dried	6 months	Not applicable	18 months.
Streptokinase	Not applicable	.....do	Do.
Tetanus and Diphtheria Toxoids Adsorbed for Adult Use.	1 year	.....do	2 years.
Tetanus Antitoxin:			
1. Liquid	.....do	.....do	5 years with an initial 20 percent excess or potency.
2. Dried	.....do	2 years	5 years with an initial 10 percent excess or potency.
Tetanus Toxoid	.....do	Not applicable	2 years.
Tetanus Toxoid Adsorbed	.....do	.....do	Do.
Thrombin	.....do	2 year	3 years.
Thrombin Impregnated Pad	Not applicable	Not applicable	1 year, or 6 months at 20 to 24 °C.
Tuberculin:			
1. Purified Protein Derivative, diluted.	6 months	.....do	1 year.
2. Old or Purified Protein Derivative dried on multiple puncture device.	1 year (not to exceed 30 °C; do not refrigerate).	.....do	2 years, provided labeling recommends storage at a temperature not to exceed 30 °C. Do not refrigerate.
3. Old on multiple puncture device.	.....do	.....do	Do.
Typhoid Vaccine	1 year	.....do	18 months.
ACD Whole Blood	Not applicable	.....do	21 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
CPD Whole Blood	.....do	.....do	Do.
CPDA–1 Whole Blood	.....do	.....do	35 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
Heparin Whole Blood	.....do	.....do	48 hours from date of collection, provided labeling recommends storage between 1 and 6 °C.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Yellow Fever Vaccine	.....do	1 year (−20 °C or colder).	1 year, provided labeling recommends storage at 5 °C or colder.

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, issued by the Director, Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research.

[50 FR 4134, Jan. 29, 1985, as amended at 51 FR 15607, Apr. 25, 1986; 51 FR 19750, June 2, 1986; 52 FR 37450, Oct. 7, 1987; 53 FR 12764, Apr. 19, 1988; 62 FR 15110, Mar. 31, 1997; 64 FR 56453, Oct. 20, 1999; 70 FR 14985, Mar. 24, 2005; 72 FR 45887, Aug. 16, 2007; 72 FR 54208, Sept. 24, 2007; 73 FR 49942, Aug. 25, 2008]

Subpart G—Labeling Standards

§ 610.60 Container label.

(a) *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

(1) The proper name of the product;

(2) The name, address, and license number of manufacturer;

(3) The lot number or other lot identification;

(4) The expiration date;

(5) The recommended individual dose, for multiple dose containers.

(6) The statement: ''Rx only'' for prescription biologicals.

(7) If a Medication Guide is required under part 208 of this chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a Medication Guide to each patient to whom the drug is dispensed and stating how the Medication Guide is provided, except where the container label is too small, the required statement may be placed on the package label.

(b) *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.

(c) *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.

(d) *No container label.* If the container is incapable of bearing any label, the items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label.

(e) *Visual inspection.* When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

[38 FR 32056, Nov. 20, 1973, as amended at 47 FR 22518, May 25, 1982; 63 FR 66400, Dec. 1, 1998; 67 FR 4907, Feb. 1, 2002]

§ 610.61 Package label.

The following items shall appear on the label affixed to each package containing a product:

(a) The proper name of the product;

(b) The name, address, and license number of manufacturer;

(c) The lot number or other lot identification;

(d) The expiration date;

(e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words ''no preservative'';

(f) The number of containers, if more than one;

(g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for